Exactech®

2320 NW 66TH COURT
GAINESVILLE, FL 32653
352-377-1140
FAX 352-378-2617

K043403

DEC 28 2004

Tecres
Cemex® System Genta Fast bone cement
Special 510(k)

Summary of Safety and Effectiveness

Trade Names: Cemex System Genta Fast bone cement

Common Name: Bone Cement

Classification Name: Polymethylmethacrylate (PMMA) Bone Cement

Legally Marketed Device for Substantial Equivalence Comparison:

Model	Manufacturer	510(k) Number
Cemex Genta Cemex System Genta	Tecres, S.p.A.	#K033596

INDICATIONS FOR USE

Cemex System Genta Fast Bone Cement is indicated for the fixation of prostheses to living bone in the second stage of a two-stage revision for total joint arthroplasty after the initial infection has been cleared.

CONTRAINDICATIONS

Cemex System Genta Fast Bone Cement **is contraindicated in primary orthopaedic musculoskeletal surgical procedures**.

Cemex System Genta Fast Bone Cement is contraindicated in patients who are allergic or sensitive to any of its components, including Gentamicin Sulphate.

If the patient has a history of hypersensitivity or serious toxic reactions to aminoglycosides, the use of any other aminoglycosides may also be contraindicated due to the known cross-sensitivity of patients to drugs in this class.

Cemex System Genta Fast Bone Cement is contraindicated in the presence of active or incompletely treated infection, at the site where the bone cement is to be applied.

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Cemex System Genta Fast Bone Cement is contraindicated where the loss of musculature or neuromuscular compromise in the affected limb would render the surgical procedure unjustifiable.

Cemex System Genta Fast Bone Cement must be considered carefully in the presence of myastenia gravis.

There may be increased risk of ototoxicity from gentamicin, if other ototoxic drugs such as cisplatin (an antineoplatic agent) and vancomycin (another antibiotic) are given at the same time. There also appears to be a synergistic effect of loop diuretics, such as furosemide or ethacrynic acid, and also loud noise, when combined with gentamicin.

GENERAL DESCRIPTION – Substantial Equivalency Information

The individual chemical constituents in **Cemex System Genta Fast** bone cement are identical to those in the predicate **Cemex Genta / Cemex System Genta** bone cement (#K033596). The liquid component contains methylmethacrylate, N-N dimethyl p-toluidine, and hydroquinone. The dry powder component contains polymethylmethacrylate, barium sulphate, benzoyl peroxide and gentamicin sulphate.

The only difference is that the predicate Cemex Genta / Cemex Genta System has a 2.7:1 powder-to-liquid ratio compared to the 2.4:1 ratio the new Cemex System Genta Fast product. The powder-to-liquid ratio reduction results in a quicker setting time to accommodate various application techniques.

Performance testing shows that the proposed device is equivalent to the predicate and meet the requirements of ISO 5833 and ASTM 451-99. Performance testing shows that the rate of gentamicin release is within the safety range and comparable to the predicate Cemex Genta.

PACKAGING

Cemex System Genta Fast bone cement is packaged similarly to the predicate **Cemex System Genta** bone cement. The device is contained into the same double blister pack used for the predicate. The blisters are sealed with Tyvek® lids. The double blister pack is positioned inside an aluminum bag. The outer packaging is a heavy weight cardboard box.

MIXING & APPLICATION

Use of Cemex System Genta Fast bone cement takes place in two consecutive stages. During the first stage, the glass ampoule containing the liquid monomer is broken to allow the component to flow into the chamber containing the powdered constituents. The device is then

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used as a closed manual mixing device. Mixing is accomplished by firmly striking the device against the palm of the hand and rotating at each strike. Because no direct contact is made between the components and the user, volitile release into the local environment and possibility of contamination is minimized. In the second stage, the container is attached to an application gun device and used as a syringe while the cement is still in a semi-fluid state. The transparency of the mixing device provides for preliminary inspection of the suitability of the cement components and the visualization of the mixing and application stages as required by ISO 5833. Detailed instructions for use and precaution/warning information is outlined in the instruction leaflet provided with the product.

STERILITY ASSURANCE

The powdered component is sterilized by ethylene oxide (EO) to a Sterility Assurance Level (SAL) of 10^{-6}. The liquid component is sterilized by a membrane filtration technique to a SAL of 10^{-3}.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 28 2004

Ms. Lisa Simpson
Sr. Regulatory Representative
Exactech, Inc.
2320 NW 66th Court
Gainesville, Florida 32653

Re: K043403
Trade Name: Cemex System Genta Fast Bone Cement
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: II
Product Code: LOD
Dated: December 16, 2004
Received: December 20, 2004

Dear Ms. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

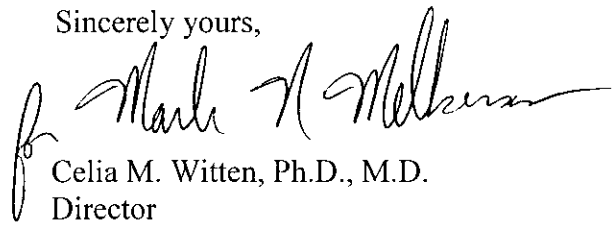
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Tecres
Cemex® System Genta Fast Bone Cement
Indications for Use

510(k) Number: [redacted] K043403

Device Names: **Cemex System Genta Fast Bone Cement**

INDICATIONS FOR USE

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Prescription Use ___X___ or Over the Counter Use _____

Please do not write below this line - use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043403